510 (k) Summary of Safety and Effectiveness

K081196

OCT 1 6 2008

Date Summary Prepared: April 25, 2008

Submitter Information: Spinal USA
644 Lakeland East Drive Suite A
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Contact Name: Jeffrey Johnson
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Device Trade Name: Intervertebral Body Fusion Device

Common Name: Intervertebral Body Fusion Device

Regulatory Number: 888.3080
Classification: Class II
Product Code: MAX

INTENDED USE:

The Spinal USA Interbody Fusion Device is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space for the ALIF and TLIF system. Two devices are used per intervertebral space for the PLIF system.

The Spinal USA Interbody Fusion Device ALIF, PLIF, TLIF System are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used with supplemental fixation and autogenuos bone graft. Patients should have at least six months of non-operative treatment prior to treatment with a lumbar intervertebral fusion device.

DEVICE DESCRIPTION:

The Spinal USA Interbody Fusion Device consists of implants with various widths, heights and lengths to accommodate individual patient anatomy and graft material size. All components are manufactured from medical grade polyetheretherketone (Peek, LT1). The products are supplied clean and "NON-STERILE".

EQUIVALENT DEVICE:

Documentation was provided which demonstrated the Spinal USA Interbody Fusion Device to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in intended use, indications, anatomic sites, performance and material of manufacture. The predicate devices are Depuy Spine-Brantigan I/F Cage (P960025), Synthes Synfix Spacer (K072253), Medicrea Technologies-Implex Spacer (K072226), Stryker Spine-Avs PL Peek Spacer (K073470), Stryker Spine-Avs PL Peek Spacer (K080758)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2008

Spinal USA
% Mr. Jeffrey Johnson
Manager, Regulatory Affairs
644 Lakeland East Drive, Suite A
Flowood, Mississippi 39232

Re: K081196
Trade/Device Name: Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: September 05, 2008
Received: September 05, 2008

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081196

Device Name: Interbody Fusion Device

Indications for Use:

The Spinal USA Interbody Fusion Device is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space for the ALIF and TLIF system. Two devices are used per intervertebral space for the PLIF system.

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Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081196